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August 6, 2007

BY ELECTRONIC FILING AND HAND DELIVERY

Hon. Patty Shwartz
United States Magistrate Judge
Post Office Building & U.S. Courthouse
50 Walnut Street, Room 10
Newark, New Jersey 07102

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Re: *Novartis et al. v. Roxane* (2:06-cv-04125 (FSH))
Novartis et al. v. Taro et al. (2:06-cv-04178 (FSH))
Novartis et al. v. Breckenridge (2:06-cv-04199 (FSH))
Novartis et al. v. Teva et al. (2:06-cv-04200 (FSH))

Dear Judge Shwartz:

We, along with Fitzpatrick, Cella, Harper & Scinto, represent the Novartis plaintiffs in these Hatch-Waxman patent infringement actions. Pursuant to Local Rule 7.1(i), we write to seek reconsideration of Your Honor's Order of July 23, 2007 (2:06-cv-4200, Document 37) ("Order") to the extent it overruled the objections of Novartis to "the production of discovery [in response to defendants' document requests] concerning secondary considerations". In our view, Novartis plainly has already produced the documents sought by the document requests at issue. Defendants disagree. Out of an abundance of caution and in light of defendants' position and the general importance of this discovery issue, Novartis feels compelled to seek reconsideration.

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Summary

Defendants' Document Requests 30-37 (Exh. A at 31-36) seek documents related to any "secondary consideration" believed by Novartis to be relevant to the obviousness issue (Req. 30), and documents concerning any of several specifically-identified "alleged" secondary considerations (Reqs. 31-37).[1] Novartis alleges two secondary considerations--unexpected results and defendants' copying of the patented invention; it does not rely on commercial success. Therefore, in response to defendants' Document Requests 30-37, Novartis agreed to produce -- and has

[1] The normal meaning of "alleged" in this legal context is "claimed to be true". Thus, the only reasonable interpretation of defendants' Document Requests 31-37 is that they seek only documents concerning any claim by Novartis that secondary considerations exist. Defendants certainly would not, and do not, claim that any secondary consideration exists.

produced -- non-privileged documents related to those two alleged secondary considerations. (Exh. A at 31-36).[2]

Defendants now want more than this, however. They argued, both in the July 10, 2007 joint letter to Your Honor ("Joint Letter") (Exh. B) and during the July 20, 2007 telephone conference on various discovery disputes (transcript excerpts attached as Exhibit C), that, because Novartis has "injected" two specific secondary considerations into the case, they have the right to discovery on other, unasserted secondary considerations to "counter" or "balance" Novartis's arguments. (Joint Letter, Exh. B, at 11; July 20 Tr., Exh. C, at 54).

During the July 20 telephone conference, the Court expressed the view that all secondary considerations "need to be balanced among themselves to see which ones should be provided more weight than others." (July 20 Tr., Exh. C, at 57). Based on that view, the Court ruled that, to the extent Novartis objected to defendants' document requests on the ground that unasserted secondary considerations are irrelevant, the objections are overruled and "the information that's being sought on secondary considerations should be produced." (July 20 Tr., Exh. C, at 58).

Novartis respectfully submits that the parties and, as a result the Court, misapprehended the actual scope of defendants' Document Requests 30-37.[3] On their face, these requests do not seek information on unasserted secondary considerations; instead, they are limited to the alleged or asserted secondary considerations. Thus, Novartis respectfully requests that the Court reconsider its Order and deny the discovery on unasserted secondary considerations as not within the scope of defendants' document requests. Alternatively, assuming the discovery requests at issue could be read as seeking documents on unasserted secondary considerations, Novartis submits that such discovery in any event is irrelevant and should not be permitted. Thus, Novartis respectfully requests that the Court reconsider and sustain Novartis's objection on that ground.

Background and Nature of Action

In the1960s, scientists at a Novartis predecessor discovered that a chemical compound called oxcarbazepine was effective in the treatment of epileptic seizures. Novartis markets an oxcarbazepine product outside of the United States under the

[2] Defendants also complained about Novartis's response to other document requests, Nos. 49-54 and 56-59. But, Novartis has either agreed to produce documents responsive to these requests, or they plainly seek totally irrelevant information. *See* last section of this letter.

[3] Copies of these document requests were not provided to the Court with the Joint Letter.

name Trileptal®.[4] That product is marketed in the form of tablets, where the oxcarbazepine active ingredient is in the form of particles ("the original Trileptal® product"). Because the oxcarbazepine active ingredient in the original Trileptal® product is absorbed by the body to a greater extent when the patient takes it with food, as compared to without food ("the food effect"), the original Trileptal® product must be taken with food to achieve sufficient "bioavailability" (*i.e.*, the amount of active ingredient that reaches the bloodstream from an administered dosage form).

In the mid-1990s, Dr. Burkhard Schlütermann, a scientist working in Switzerland at a Novartis predecessor, discovered that oxcarbazepine of even smaller particle size - - on the order of 2-12 microns - - surprisingly provided essentially the same bioavailability with or without food. In this sense, the smaller-particle-size oxcarbazepine product provided improved bioavailability, and also better patient compliance (*i.e.*, assurance that patients taking the drug were obtaining the full therapeutic benefit irrespective of whether they took the drug with or without food).

The '525 patent claims a method of treating seizures by the administration of an oxcarbamazepine formulation having that smaller particle size. Novartis has received FDA approval for, and markets, the smaller-particle-size oxcarbazepine product ("the new Trileptal® product"). Defendants have filed Abbreviated New Drug Applications ("ANDA") seeking approval to market generic copies of Novartis's new Trileptal® product prior to the expiration of the '525 patent, triggering the present actions.

The Obviousness Analysis

Defendants allege that the '525 patent is invalid for obviousness under 35 U.S.C. §103. Under that statute, an invention is invalid for obviousness if:

> the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which such subject matter pertains.

35 U.S.C. §103(a). As explained by the Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966), Section 103 "lends itself to several basic factual inquiries":

[4] Novartis also markets a different product, Tegretol®, containing a different active ingredient, carbamazepine.

> Under 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unresolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy. See, Note, *Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity. 112 U. Pa. L. Rev. 1169 (1964).*

383 U.S. at 17-18). Subsequent decisions of the Court of Appeals for the Federal Circuit have clarified the Section 103 analysis. In particular, the Federal Circuit has made clear that the secondary considerations are useful for a patentee to rebut a conclusion of obviousness - - *i.e.*, they are indicia of nonobviousness.

Procedurally, because a patent is presumed valid, 35 U.S.C. §282, a defendant-accused-infringer bears the initial burden of establishing a *prima facie* case of obviousness under Section 103. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 291 (Fed. Cir. 1985). Once a *prima facie* case has been established, the burden shifts to the patentee to go forward with rebuttal evidence showing facts supporting nonobviousness. *Ashland Oil*, 776 F.2d at 291-92. The secondary considerations are a means for a patentee to rebut a *prima facie* case of obviousness. *See Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1293 (Fed. Cir. 2006) ("Mylan had established a strong *prima facie* case of obviousness, which Alza had failed to rebut through secondary considerations."); *Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1383 (Fed. Cir. 2005) ("As discussed in *Merck*, the secondary consideration of commercial success exists largely to provide a means for patentees to show in close cases that subject matter that appears obvious is in law unobvious because a high degree of commercial success permits the inference that others have tried and failed to reach a solution. *Merck* [*& Co., Inc. v. Teva Pharm. USA, Inc.*,] 395 F.3d [1364,] 1376 [(Fed.Cir. 2005).]"). Thus, in rejecting a patentee's argument that the opinion of an accused infringer's expert was unreliable because he did not consider all of the secondary considerations, the Delaware District Court, in *Inline Connection Corp. v. AOL Time Warner Inc.*, C.A. No. 01-272-MPT, C.A. No. 02-477, 2007 U.S.Dist. LEXIS 6207 (D. Del. January 29, 2007) (Exh. D attached), stated as follows:

> [The patentee's] argument, however, on obviousness is completely contrary to clear Federal Circuit law

> stating that secondary considerations are a means for a *patentee* (*i.e.*, Inline) to *rebut* a prima facie showing of obviousness by a defendant.

2007 U.S. Dist. LEXIS, at *16, Exh. D, citing *Alza* and *Syntex*, emphasis in original.[5]

In the present case, in order to rebut defendants' obviousness case, Novartis contends that two secondary considerations support a conclusion of non-obviousness: the unexpected results associated with the invention claimed in the '525 patent-in-suit and defendants' copying of that invention.[6] Thus, evidence relating to other, unasserted secondary considerations is irrelevant unless it impacts Novartis's evidence on its asserted unexpected results or copying--and that is not the case here (*see* discussion *infra*).

The Document Requests In Issue

In their Document Request No. 30, Defendants sought the production of:

> documents...relating to...any secondary considerations or objective indicia of non-obviousness...that plaintiffs believe are relevant to the issue of obviousness....

(Exh. A at 31, emphasis added). Because the request sought only documents relating to secondary considerations Novartis believed were relevant, Novartis did not object on relevancy grounds; instead, Novartis agreed to produce documents to the extent Novartis contended a secondary consideration supported non-obviousness, stating:

> to the extent Plaintiffs contend that the non-obviousness of the claimed subject matter of the '525 patent is supported by the secondary considerations, Plaintiffs will produce responsive, non-privileged documents located during a reasonable search.

[5] The *Inline* court further observed that *Ruiz v. A.B. Chance Co.*, 238 F.3d 654, 667 (Fed. Cir. 2000), *aff'd*, 357 F.3d 1270 (Fed. Cir. 2004), referred to by the Court here during the July 20 teleconference, merely stands for the unremarkable proposition that, when present, secondary considerations must be considered. *See Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983).

[6] Novartis has committed not to assert the secondary consideration of commercial success.

(Exh. A at 32, emphasis added).[7]

Similarly, in their Document Request No. 31, Defendants only sought the production of:

> documents...concerning...any alleged unexpected result by any invention claimed in the '525 patent.

(Exh. A at 32, emphasis added).

Because the request only sought documents concerning alleged unexpected results, Novartis did not object on relevancy grounds. Instead, as it did in response to Document Request 30, Novartis agreed:

> to the extent Plaintiffs contend that the non-obviousness of the claimed subject matter of the '525 patent is supported by the secondary consideration of unexpected results, Plaintiffs will produce non-privileged documents responsive to this request located during a reasonable search.

(Exh. A at 32-33, emphasis added).

Defendants' Document requests 32-37 similarly seek documents concerning certain other "alleged" secondary considerations. Novartis's responses to these requests mirrored its response to Document Request 31; it agreed to produce documents to the extent Novartis contends the particular secondary consideration supported non-obviousness. (Exh. A at 33-36).

In short, defendants' document requests plainly sought only documents related to secondary considerations Novartis believes to be relevant, and documents concerning secondary considerations alleged by Novartis. On their face, defendants' Document Request Nos. 30-37 did not seek the production of documents relating to unasserted secondary considerations. Because the parties overlooked the actual text of defendants' Document Requests 30-37, it is entirely understandable that the Court may not have appreciated their true scope. The fact remains that defendants are seeking discovery beyond the actual scope of their document requests. For that reason alone, the discovery sought by defendants should be denied.

[7] In a telephone discussion with defendants' counsel on April 25, 2007, Novartis clarified that, to the extent Novartis alleged any particular secondary consideration, it would produce documents both supporting and contradicting it. (May 21, 2007 Ross letter, Exh. E, at 4).

The Joint Letter and the July 20 Court Conference

The Joint Letter included the parties' positions on documents "concerning secondary considerations" responsive to defendants Document Requests 30-37.[8] (Joint Letter, Exh. B, at 9-13). In that letter, Defendants argued that once Novartis "placed into issue" the two secondary considerations alleged by Novartis (unexpected results and copying), defendants "have the right to counterbalance them," including "evidence of other secondary considerations." (Joint Letter, Exh. B, at 11). For example, defendants argued that evidence showing the lack of a "long-felt need" (another secondary consideration), or evidence that any commercial success was due to factors other than oxcarbazepine particle size, "would undercut Plaintiffs' argument that this particular 'unexpected results' was significant enough to outweigh Defendants' evidence showing that the invention was obvious." (*Id.*)

The Court heard argument from the parties during the July 20 telephone conference. (July 20 Tr., Exh. C, at 51-58). The Court, citing *Ruiz*, reasoned that a party challenging obviousness is entitled to discovery "to be able to show that the absence of secondary considerations further demonstrate[s] obviousness in -- to bolster their case" (July 20 Tr., Exh. C, at 53). The Court also reasoned that the various secondary considerations "need to be balanced among themselves to see which ones should be provided more weight than others." (July 20 Tr., Exh. C, at 57). Novartis respectfully submits that the absence of secondary considerations does not demonstrate obviousness, as defendants conceded (*see* July 20 Tr., Exh. C, at 54), and that there is no "balancing" test among secondary considerations.

The *Ruiz* and *Stratoflex* decisions stand for nothing more than the rule that all evidence on secondary considerations, when present and offered, must be considered en route to a determination on the issue of obviousness. Those cases do not stand for the proposition that the impact of a particular secondary consideration on the obviousness determination (such as Novartis' unexpected results) is somehow lessened when "balanced" against the presence or absence of some other unasserted secondary consideration. And, logically, that cannot be.

As explained above, secondary considerations are tools used by a patentee to rebut a defendant's *prima facie* case of obviousness; it is a patentee who asserts and relies on secondary considerations. Each secondary consideration should be evaluated on its own merits when asserted. For example, as discussed below, evidence relating to long-felt need cannot possibly affect the probative value of evidence related to unexpected results. They are simply different factors, are based on fundamentally different proofs, and each should be evaluated independently of the other.

[8] As an afterthought, defendants included, without any meaningful argument, document request nos. 49-54 and 56-59 (Joint Letter, Exh. B, at 11). *See* last section of this letter.

Information Related to Unasserted
Secondary Considerations is Irrelevant

Novartis agreed to produce, and has produced, the documents falling within defendants' Document Requests 30-37 - - *i.e.*, those concerning the two alleged secondary factors on which Novartis relies. Defendants are entitled to nothing further. In any event, even if these document requests are read to seek documents relating to unasserted factors, defendants are not entitled to that discovery--it is entirely irrelevant. Indeed, defendants in reality must agree with Novartis's analysis - - in their Document Requests 30-37, defendants asked for information only on secondary considerations asserted by Novartis.

The Note so heavily relied on by the Supreme Court in *Graham* (Exh. F attached) suggested that, in light of the difficulty experienced by courts in applying the legal standards of nonobviousness to technical facts, certain non-technical "subtests" should be developed:

> Some courts have developed and utilized such subtests, often called "indicia of invention." The focus of these inquiries is upon economic and motivational rather than technical issues; the facts with which to resolve such issues are more amenable to judicial treatment than are the technical facts with which the courts generally struggle.

(Note, Exh. F, at 1172). These subtests included those referenced by the Supreme Court in *Graham* (*i.e.*, long-felt need, commercial success and failure of others).[9]

A long-felt need in a particular field for a solution to a persistent problem, if solved by the patentee, demonstrates that the inventor's solution was nonobvious. As explained in the Note:

> Existence of the defect creates a demand for its correction, and it is reasonable to infer that the defect would not persist were the solution "obvious." This is the rationale of longfelt demand and its justification as a test of nonobviousness.

(*Id.*, footnote omitted). *See also In re Mahurkar Double Lumen Hemodialysis Catheter Patent Litig.*, 831 F.Supp. 1354, 1378 (N.D. Ill. 1993), *aff'd*, 71 F.3d 1573 (Fed. Cir. 1995) ("If people are clamoring for a solution, and the best minds do not

[9] The Note refers to long-felt need as "longfelt demand". (Exh. F at 1172-73).

find it for years, that is practical evidence--the kind that can't be bought from a hired expert, the kind that does not depend on fallible memories or doubtful inferences--of the state of knowledge.")

Likewise, the Note commented that failure of others to find a solution to a problem also is strong evidence of nonobviousness:

> [W]hen proof of unsuccessful research has been presented, it is improbable that the patent has been granted for knowledge already in the hands of those skilled in the art.

(Note, Exh. F, at 1175). *See also Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1354 (Fed. Cir. 2003) ("there can be little better evidence negating an expectation of success than actual reports of failure").

Also, in the Note the author commented on why commercial success is an indicium of nonobviousness:

> If in fact a product attains a high degree of commercial success, there is a basis for inferring that [attempts by innovators to solve an existing problem] have been made and have failed. Thus the rationale is similar to that of longfelt demand and is for the same reasons a legitimate test of invention.

(Note, Exh. F, at 1175).[10]

Thus, to establish long-felt need, the patentee-proponent must show the prolonged existence of a problem and that the invention-at-issue solved it. To establish commercial success, one must prove sales of a patented product whose success is due to the merits of the invention and not some other factor. And, to establish failure-of-others, one must show that other workers in the same field tried, but failed, to solve the existing problem.

On the other hand, the scientific evidence necessary to establish the secondary consideration of unexpected results is entirely different. In particular, one establishes unexpected results by showing "that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected." *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995). Here, that evidence will consist of scientific facts demonstrating that the

[10] The author also noted that the absence of commercial success can have an adverse effect only "to the extent that it rebuts any inference of a long-felt demand." (Note, Exh. F, at 1177).

improved bioavailability of the smaller-particle-size oxcarbazepine product was surprising or unexpected.

Importantly, evidence supporting or contradicting other secondary considerations has nothing to do with the scientific evidence demonstrating unexpected results. Whether improved bioavailability was surprising or unexpected logically has absolutely nothing to do with whether there was or was not a long-existing problem in the art, whether or not the invention solved that problem, whether or not others failed to solve it, or whether or not some product was commercially successful. Moreover, because discovery on these unasserted secondary considerations is entirely irrelevant, the burden on Novartis to search for and produce that information plainly significantly outweighs any possible probative value in this litigation.

Defendants' Document Requests 49-54, 56-59

Defendants' Document Requests 49-54 and 56-59 seek documents relating to oxcarbazepine advertisements (Nos. 50, 51); oxcarbazepine sales and marketing (Nos. 49, 56-59); and carbamazepine sales and marketing (Nos. 52-54). (Exh. A at 43-50). To the extent the Order compels Novartis to produce documents responsive to these requests, Novartis respectfully submits that the Order was overbroad. Novartis respectfully requests that the Court reconsider and sustain Novartis's objections.

First, Novartis has agreed to produce oxcarbazepine advertisements; so Request Nos. 50 and 51 should not be in dispute.

Second, documents related to oxcarbazepine sales and marketing are only potentially relevant to commercial success. Such information cannot possibly impact the scientific evidence as to whether Novartis's invention provided the unexpected result of improved bioavailability. For example, sales volumes or marketing procedures will shed no light on whether a person of ordinary skill in the art would have expected a reduction in oxcarbazepine particle size to result in improved bioavailability. Instead, what will shed light on that issue are facts such as what the skilled person would expect, the nature of just how improved the bioavailability is, etc. The requested documents simply could not possibly be probative of unexpected results.

Finally, defendants' document requests seeking carbamazepine sales and marketing documents (Nos. 52-54) are even farther afield. Sales and marketing of a product different from the product whose use is covered by the patent-in-suit cannot reasonably be expected to be probative of the nonobviousness of those claims. Defendants have articulated no good reason why they are entitled to this discovery, and there is none.

The Court should sustain Novartis's objection to these requests.

* * *

For the above reasons, Novartis respectfully requests that Your Honor reconsider the Order and sustain Novartis's objections to Defendants' Document Request Nos. 30-37, 49-54 and 56-59.

Respectfully,

William J. O'Shaughnessy

William J. O'Shaughnessy

cc: All Counsel of Record

Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION and NOVARTIS AG, Plaintiffs, v. ROXANE LABORATORIES, INC., Defendant.	Civil Action No. 2:06-cv-04125 (FHS)(PS) **PLAINTIFFS' RESPONSE TO DEFENDANTS' JOINT DOCUMENT REQUEST**

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION and NOVARTIS AG, Plaintiffs, v. TARO PHARMACEUTICALS USA, INC., and TARO PHARMACEUTICAL INDUSTRIES, LTD. Defendants.	:	Civil Action No. 2:06-cv-04178 (FSH)(PS)
NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION and NOVARTIS AG, Plaintiffs, v. BRECKENRIDGE PHARMACEUTICAL, INC., Defendant.	:	Civil Action No. 2:06-cv-04199 (FSH)
NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION and NOVARTIS AG, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	:	Civil Action No. 2:06-cv-4200 (FSH)

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION and NOVARTIS AG, Plaintiffs, v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD. Defendants.	:	Civil Action No. 2:06-cv-04550 (FSH)(PS)

PLAINTIFFS' RESPONSE TO DEFENDANTS' FIRST JOINT REQUEST FOR PRODUCTION OF DOCUMENTS AND THINGS TO PLAINTIFFS NOS. 1-79

Pursuant to Rule 34 of the Federal Rules of Civil Procedure and the Local Civil Rules of the United States District Court for the District of New Jersey, Plaintiffs Novartis Pharmaceuticals Corporation, Novartis Corporation and Novartis AG (collectively "Novartis" or "Plaintiffs") hereby respond to Defendants Roxane Laboratories, Inc., Taro Pharmaceuticals USA, Inc., Taro Pharmaceutical Industries, Ltd., Breckenridge Pharmaceutical, Inc., Teva Pharmaceuticals USA, Inc., Dr. Reddy's Laboratories, Inc., and Dr. Reddy's Laboratories, Ltd. (collectively "Defendants'") First Joint Request for Production of Documents and Things to Plaintiffs served on January 12, 2007 ("Joint Document Request").

finely ground oxcarbazepine or its use in treating seizures, but only to the extent such documents are located during a reasonable search for documents responsive to other requests. The production of such documents by Plaintiffs is not an admission that such documents qualify as prior art to the '525 patent.

REQUEST NO. 29

All documents and things concerning any prior art referring to the effect of particle size on bioavailability or similar to the '525 patent (as defined by 35 U.S.C. § 102) including but not limited to patents, publications, internal documents, sales, offers for sale or uses of the subject matter of such patents related to: any carbamazepine product and/or its use to treat convulsions and/or seizures and any related disorders and/or symptoms of such disorders.

RESPONSE TO REQUEST NO. 29

Plaintiffs object to this request as overly broad and unduly burdensome, and as seeking the production of documents that are neither relevant to any claim or defense of a party in this action nor reasonably calculated to lead to the discovery of admissible evidence, to the extent the request seeks the production of "all" documents "concerning," or documents related to "any prior art" or "similar" to the '525 patent or "any" "related disorders," or documents related to "any" "carbamazepine" product.

Plaintiffs further object to this request as vague and ambiguous; for example, the request imprecisely calls for the production of "[a]ll documents . . . concerning any prior art . . . including . . . patents, publications, internal documents . . . related to . . . any carbamazepine product and/or its use to treat . . . ." The scope of the request is unclear.

REQUEST NO. 30

All documents and things relating to concerning, supporting or contradicting any secondary considerations or objective indicia of non-obviousness (as these terms are used in Graham v. John Deere Co., 383 U.S. 1, 19 (1966), citing *Subtests of 'Nonobviousness': A Nontechnical Approach to Patent Validity*, 112 U.Pa.L.Rev. 1169 (1964)) that plaintiffs believe are relevant to the issue of the obviousness of any invention claimed in the '525 patent.

RESPONSE TO REQUEST NO. 30

Plaintiffs object to this request to the extent it seeks the production of documents protected from discovery by the attorney-client privilege or work-product immunity.

Plaintiffs object to this request on the grounds that it is premature. Plaintiffs further object to this request on the ground that Defendants bear the burden of demonstrating invalidity under 35 U.S.C. § 103. However, to the extent Plaintiffs contend that the non-obviousness of the claimed subject matter of the '525 patent is supported by the secondary considerations, Plaintiffs will produce responsive, non-privileged documents located during a reasonable search.

Plaintiffs further object to this request as vague and ambiguous; for example, the meaning and significance of the terminology "citing . . . (1964))" is unclear and imprecise. Hence, the scope of the request cannot reasonably be ascertained.

REQUEST NO. 31

All documents and things concerning, supporting or contradicting any alleged unexpected result by any invention claimed in the '525 patent.

RESPONSE TO REQUEST NO. 31

Plaintiffs object to this request to the extent it seeks the production of documents protected from discovery by the attorney-client privilege or work-product immunity.

Plaintiffs object to this request on the grounds that it is premature. Plaintiffs further object to this request on the ground that Defendants bear the burden of demonstrating invalidity under 35 U.S.C. § 103. However, to the extent Plaintiffs contend that the non-obviousness of the claimed subject matter of the '525 patent is supported by the secondary

consideration of unexpected results, Plaintiffs will produce non-privileged documents responsive to this request located during a reasonable search.

REQUEST NO. 32

All documents and things concerning, supporting or contradicting any alleged skepticism or doubt about any invention claimed in the '525 patent.

RESPONSE TO REQUEST NO. 32

Plaintiffs object to this request to the extent it seeks the production of documents protected from discovery by the attorney-client privilege or work-product immunity.

Plaintiffs object to this request on the grounds that it is premature. Plaintiffs further object to this request on the ground that Defendants bear the burden of demonstrating invalidity under 35 U.S.C. § 103. However, to the extent Plaintiffs contend that the non-obviousness of the claimed subject matter of the '525 patent is supported by the secondary consideration of skepticism and doubt by others, Plaintiffs will produce non-privileged documents responsive to this request located during a reasonable search.

REQUEST NO. 33

All documents and things concerning, supporting or contradicting any alleged long felt need met by any invention claimed in the '525 patent.

RESPONSE TO REQUEST NO. 33

Plaintiffs object to this request to the extent it seeks the production of documents protected from discovery by the attorney-client privilege or work-product immunity.

Plaintiffs object to this request on the grounds that it is premature. Plaintiffs further object to this request on the ground that Defendants bear the burden of demonstrating invalidity under 35 U.S.C. § 103. However, to the extent Plaintiffs contend that the non-obviousness of the claimed subject matter of the '525 patent is supported by the secondary

consideration of long felt need, Plaintiffs will produce non-privileged documents responsive to this request located during a reasonable search.

REQUEST NO. 34

All documents and things concerning, supporting or contradicting any alleged commercial success of any products related to any invention claimed in the '525 patent.

RESPONSE TO REQUEST NO. 34

Plaintiffs object to this request to the extent it seeks the production of documents protected from discovery by the attorney-client privilege or work-product immunity.

Plaintiffs object to this request on the grounds that it is premature. Plaintiffs further object to this request on the ground that Defendants bear the burden of demonstrating invalidity under 35 U.S.C. § 103. However, to the extent Plaintiffs contend that the non-obviousness of the claimed subject matter of the '525 patent is supported by the secondary consideration of commercial success, Plaintiffs will produce non-privileged documents responsive to this request located during a reasonable search.

REQUEST NO. 35

All documents and things concerning, supporting or contradicting any alleged failure of others of any products related to any invention claimed in the '525 patent.

RESPONSE TO REQUEST NO. 35

Plaintiffs object to this request to the extent it seeks the production of documents protected from discovery by the attorney-client privilege or work-product immunity.

Plaintiffs object to this request on the grounds that it is premature. Plaintiffs further object to this request on the ground that Defendants bear the burden of demonstrating invalidity under 35 U.S.C. § 103. However, to the extent Plaintiffs contend that the non-obviousness of the claimed subject matter of the '525 patent is supported by the secondary

consideration of failure by others, Plaintiffs will produce non-privileged documents responsive to this request located during a reasonable search.

REQUEST NO. 36

All documents and things concerning, supporting or contradicting any alleged problem, or criticism of any product, formulation or compound substantially comprised of oxcarbazepine API particles larger than 40 μm.

RESPONSE TO REQUEST NO. 36

Plaintiffs object to this request to the extent it seeks the production of documents protected from discovery by the attorney-client privilege or work-product immunity.

Plaintiffs object to this request on the grounds that it is premature. Plaintiffs further object to this request on the ground that Defendants bear the burden of demonstrating invalidity under 35 U.S.C. § 103. However, to the extent Plaintiffs contend that the non-obviousness of the claimed subject matter of the '525 patent is supported by the secondary consideration of problems or criticisms by others, Plaintiffs will produce non-privileged documents responsive to this request located during a reasonable search.

REQUEST NO. 37

All documents and things concerning any alleged awards, praise, recognition or honors received concerning any invention claimed in the '525 patent.

RESPONSE TO REQUEST NO. 37

Plaintiffs object to this request to the extent it seeks the production of documents protected from discovery by the attorney-client privilege or work-product immunity.

Plaintiffs object to this request on the grounds that it is premature. Plaintiffs further object to this request on the ground that Defendants bear the burden of demonstrating invalidity under 35 U.S.C. § 103. However, to the extent Plaintiffs contend that the non-

obviousness of the claimed subject matter of the '525 patent is supported by the secondary consideration of awards, praise, recognition or honors, Plaintiffs will produce non-privileged documents responsive to this request located during a reasonable search.

REQUEST NO. 38

All documents and things concerning any issued United States or foreign patent concerning any oxcarbazepine product assigned to, owned by, or controlled by Novartis or listing Burkhard Schlütermann as an inventor.

RESPONSE TO REQUEST NO. 38

Plaintiffs object to this request to the extent it seeks the production of documents protected from discovery by the attorney-client privilege or work-product immunity.

Plaintiffs object to this request as overly broad and unduly burdensome, and as seeking the production of documents that are neither relevant to any claim or defense of a party in this action nor reasonably calculated to lead to the discovery of admissible evidence, to the extent the request seeks the production of "all" documents "concerning" the identified subject matter, or documents "concerning" "foreign patents," or documents "concerning" "any" "oxcarbazepine" beyond the subject matter of the invention of the '525 patent in suit, or documents "concerning" patents not owned by any plaintiff.

Plaintiffs further object to this request as vague and ambiguous; for example, the request is unclear and imprecise to the extent it calls for the production of "[a]ll documents concerning" such patents. To the extent the request is construed as literally seeking the production of "all" such documents, Plaintiffs object to it as overly broad and unduly burdensome, and as seeking the production of documents that are neither relevant to any claim or defense of a party in this action nor reasonably calculated to lead to the discovery of admissible evidence.

REQUEST NO. 48

All publications, articles, abstracts, posters, presentations, seminars, speeches, lectures or talks written or given by the inventor of the '525 patent (alone or in conjunction with others) and other of plaintiffs' employees, referring or relating to any oxcarbazepine product.

RESPONSE TO REQUEST NO. 48

Plaintiffs object to this request as overly broad and unduly burdensome, and as seeking the production of documents that are neither relevant to any claim or defense of a party in this action nor reasonably calculated to lead to the discovery of admissible evidence, to the extent the request seeks the production of "all" such publications, articles, abstracts, posters, presentations, seminars, speeches, lectures or talks, or documents related to "any" "oxcarbazepine" product beyond the subject matter of the invention of the '525 patent in suit.

Subject to and without waiver of the foregoing general and specific objections, Plaintiffs will produce responsive non-privileged documents to the extent they are located during reasonable searches for documents responsive to other requests.

REQUEST NO. 49

Documents sufficient to describe sales of all oxcarbazepine products (U.S. and worldwide).

RESPONSE TO REQUEST NO. 49

Plaintiffs object to this request to the extent it seeks the production of documents protected from discovery by the attorney-client privilege or work-product immunity.

Plaintiffs further object to this request as overly broad and unduly burdensome, and as seeking the production of documents that are neither relevant to any claim or defense of a party in this action nor reasonably calculated to lead to the discovery of admissible evidence, to

the extent the request seeks the production of documents relating to "all" oxcarbazepine products or "worldwide" sales.

Plaintiffs object to this request on the grounds that it is premature. Plaintiffs further object to this request on the ground that Defendants bear the burden of demonstrating invalidity under 35 U.S.C. § 103. However, to the extent Plaintiffs contend that the non-obviousness of the claimed subject matter of the '525 patent is supported by the secondary consideration of commercial success, Plaintiffs will produce non-privileged documents responsive to this request located during a reasonable search. Furthermore, the requested documents are relevant only to the extent Plaintiffs assert commercial success as an objective indicium of non-obviousness.

REQUEST NO. 50

Each advertisement for any oxcarbazepine product.

RESPONSE TO REQUEST NO. 50

Plaintiffs object to this request as overly broad and unduly burdensome, and as seeking the production of documents that are neither relevant to any claim or defense of a party in this action nor reasonably calculated to lead to the discovery of admissible evidence, to the extent the request seeks the production of each advertisement for "any" "oxcarbazepine" product beyond the subject matter of the invention of the '525 patent in suit.

Subject to and without waiver of the foregoing general and specific objections, Plaintiffs will produce each advertisement run by Plaintiffs in the United States for its Trileptal® oxcarbazepine product, to the extent they exist and are located by a reasonable search.

REQUEST NO. 51

All document and things concerning any characterization, correction, criticism, comment and/or change to any advertisement for any oxcarbazepine product.

RESPONSE TO REQUEST NO. 51

Plaintiffs object to this request as overly broad and unduly burdensome, and as seeking the production of documents that are neither relevant to any claim or defense of a party in this action nor reasonably calculated to lead to the discovery of admissible evidence, to the extent the request seeks the production of "all" documents "concerning" the identified subject matter or documents related to "any" "oxcarbazepine" product beyond the subject matter of the invention of the '525 patent in suit.

Plaintiffs further object to the request as vague and ambiguous; for example, the terms "characterization" and "correction" and "criticism" and "comment" and "change" are unclear and imprecise. The scope of the request therefore is not reasonably ascertainable.

Subject to and without waiver of the foregoing general and specific objections, Plaintiffs will produce non-privileged documents sufficient to show the history of each advertisement run by Plaintiffs in the United States for the Trileptal® oxcarbazepine product, or documents related to "any" "characterization" or "correction" or "criticism" or "comment" or "change" to any such advertisement to the extent they exist and are located by a reasonable search.

REQUEST NO. 52

Documents sufficient to describe sales of all carbamazepine products (U.S. and worldwide).

RESPONSE TO REQUEST NO. 52

Plaintiffs object to this request as overly broad and unduly burdensome, and as seeking the production of documents that are neither relevant to any claim or defense of a party in this action nor reasonably calculated to lead to the discovery of admissible evidence.

REQUEST NO. 53

Each advertisement for any carbamazepine product.

RESPONSE TO REQUEST NO. 53

Plaintiffs object to this request as overly broad and unduly burdensome, and as seeking the production of documents that are neither relevant to any claim or defense of a party in this action nor reasonably calculated to lead to the discovery of admissible evidence.

REQUEST NO. 54

All document and things concerning any characterization, correction, criticism, comment and/or change to any advertisement for any carbamazepine product.

RESPONSE TO REQUEST NO. 54

Plaintiffs object to this request as overly broad and unduly burdensome, and as seeking the production of documents that are neither relevant to any claim or defense of a party in this action nor reasonably calculated to lead to the discovery of admissible evidence.

REQUEST NO. 55

A printout of each and every page from all of plaintiffs' prior and current Internet web sites, if any, concerning any antiseizure or anticonvulsive regimens, oxcarbazepine product, and/or the '525 patent.

RESPONSE TO REQUEST NO. 55

Plaintiffs object to this request as overly broad and unduly burdensome, and as seeking the production of documents that are neither relevant to any claim or defense of a party

in this action nor reasonably calculated to lead to the discovery of admissible evidence, to the extent the request seeks the production of website pages currently available to Defendants, or "each and every page" of prior and current Internet web sites or "regimens" or "any" "oxcarbazepine" product beyond the subject matter of the invention of the '525 patent in suit.

Subject to and without waiver of the foregoing general and specific objections, Plaintiffs will produce documents not currently publicly available on Plaintiffs' website and in Plaintiffs' possession, custody or control, to the extent they exist and are located by a reasonable search.

REQUEST NO. 56

All documents and things concerning the training of agents, licensees or employees of Novartis regarding the marketing and/or sale of any oxcarbazepine product.

RESPONSE TO REQUEST NO. 56

Plaintiffs object to this request as seeking the production of documents that are neither relevant to any claim or defense of a party in this action nor reasonably calculated to lead to the discovery of admissible evidence.

Plaintiffs further object to this request as overly broad and unduly burdensome to the extent it seeks the production of "all" documents "concerning" "any" oxcarbazepine produced beyond the subject matter of the invention of the '525 patent.

REQUEST NO. 57

All document and things concerning projected sales (in units and dollars), costs, pricing, profits or margin, pricing, marketing, market share, sales volume, market projections or analyses, or consumer profiles concerning any oxcarbazepine product.

RESPONSE TO REQUEST NO. 57

Plaintiffs object to this request to the extent it seeks the production of documents protected from discovery by the attorney-client privilege or work-product immunity.

Plaintiffs further object to this request as overly broad and unduly burdensome, and as seeking the production of documents that are neither relevant to any claim or defense of a party in this action nor reasonably calculated to lead to the discovery of admissible evidence, to the extent the request seeks the production of documents relating to "any" oxcarbazepine products beyond the subject matter of the invention of the '525 patent in suit.

Plaintiffs object to this request on the grounds that it is premature. Plaintiffs further object to this request on the ground that Defendants bear the burden of demonstrating invalidity under 35 U.S.C. § 103. However, to the extent Plaintiffs contend that the non-obviousness of the claimed subject matter of the '525 patent is supported by the secondary consideration of commercial success, Plaintiffs will produce non-privileged documents responsive to this request located during a reasonable search. Furthermore, the requested documents are relevant only to the extent Plaintiffs assert commercial success as an objective indicium of non-obviousness.

REQUEST NO. 58

All documents and things concerning sales reports, summaries, analyses, projections, histories, graphs, tables, market share analyses, reports, summaries, geographic sales territories, price studies, business plans, strategic plans, marketing plans, and economic studies relating to any oxcarbazepine product, both in and outside the Unites States.

RESPONSE TO REQUEST NO. 58

Plaintiffs object to this request to the extent it seeks the production of documents protected from discovery by the attorney-client privilege or work-product immunity.

Plaintiffs further object to this request as overly broad and unduly burdensome, and as seeking the production of documents that are neither relevant to any claim or defense of a party in this action nor reasonably calculated to lead to the discovery of admissible evidence, to the extent the request seeks the production of "all" documents "concerning" the identified subject matter, or documents relating to the identified subject matter "outside of the United States", or documents relating to "any" oxcarbazepine products beyond the subject matter of the invention of the '525 patent in suit.

Plaintiffs object to this request on the grounds that it is premature. Plaintiffs further object to this request on the ground that Defendants bear the burden of demonstrating invalidity under 35 U.S.C. § 103. However, to the extent Plaintiffs contend that the non-obviousness of the claimed subject matter of the '525 patent is supported by the secondary consideration of commercial success, Plaintiffs will produce non-privileged documents responsive to this request located during a reasonable search. Furthermore, the requested documents are relevant only to the extent Plaintiffs assert commercial success as an objective indicium of non-obviousness.

REQUEST NO. 59

All documents and things concerning industry data or reports generated by a third party relating to the sale or prescribing of products labeled for use in the treatment of seizures, bipolar disorder and/or epilepsy.

RESPONSE TO REQUEST NO. 59

Plaintiffs object to this request to the extent it seeks the production of documents protected from discovery by the attorney-client privilege or work-product immunity.

Plaintiffs object to this request on the grounds that it is premature. Plaintiffs further object to this request on the ground that Defendants bear the burden of demonstrating

invalidity under 35 U.S.C. § 103. However, to the extent Plaintiffs contend that the non-obviousness of the claimed subject matter of the '525 patent is supported by the secondary consideration of commercial success, Plaintiffs will produce non-privileged documents responsive to this request located during a reasonable search. Furthermore, the requested documents are relevant only to the extent Plaintiffs assert commercial success as an objective indicium of non-obviousness.

Plaintiffs further object to this request as overly broad and unduly burdensome, and as seeking the production of documents that are neither relevant to a claim or defense of a party in this action nor reasonably calculated to lead to the discovery of admissible evidence, to the extent it seeks the production of "all" documents "concerning" the identified subject matter, or documents related to the treatment of "bipolar disorder and/or epilepsy."

REQUEST NO. 60

All corporate resolutions, minutes, public disclosures, press releases, or other documents concerning oxcarbazepine, any oxcarbazepine product, the '525 patent, this litigation and/or any other litigation concerning oxcarbazepine, any oxcarbazepine product or the '525 patent.

RESPONSE TO REQUEST NO. 60

Plaintiffs object to this request to the extent it seeks the production of documents protected from discovery by the attorney-client privilege or work-product immunity.

Plaintiffs further object to this request as vague and ambiguous, overly broad and unduly burdensome, and as seeking the production of documents that are neither relevant to any claim or defense of a party in this action nor reasonably calculated to lead to the discovery of admissible evidence, to the extent the request seeks the production of "all" "corporate resolutions" or "minutes" or "public disclosures" or "other documents" "concerning" the

Exhibit B

McCARTER ENGLISH
ATTORNEYS AT LAW

July 10, 2007

BY ELECTRONIC FILING

Hon. Patty Shwartz
United States Magistrate Judge
Post Office Building & U.S. Courthouse
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Newark, New Jersey 07102

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Re: *Novartis et al. v. Roxane* (2:06-cv-04125 (FSH))
Novartis et al. v. Taro et al. (2:06-cv-04178 (FSH))
Novartis et al. v. Breckenridge (2:06-cv-04199 (FSH))
Novartis et al. v. Teva et al. (2:06-cv-04200 (FSH))

Joint Letter re: Unresolved Discovery Disputes

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Dear Judge Shwartz:

Pursuant to paragraph 6 of the Scheduling Order of January 5, 2007, as modified by the Order dated June 26, 2007 (Document no. 47), the parties submit this joint letter to outline for Your Honor the following unresolved fact discovery disputes: (A) Defendants' issues regarding Novartis's Response to Defendants' Document Requests, (B) Novartis's issues with regard to the refusals of Defendants Breckenridge, Roxane and Teva to produce samples of their proposed ANDA product and the oxcarbazepine they intend to use in their proposed ANDA product, (C) Novartis's issues regarding Defendants' Responses to Interrogatories, and (D) Defendants' issues concerning Novartis's Responses to Interrogatories.

As a preliminary matter, the parties note that they have conducted a number of "meet and confer" sessions, and have narrowed their disputes to the following:

A. Defendants' issues regarding Novartis's response to certain document requests

1. Documents Relating to Carbamazepine.

Defendants' position:

Defendants' Joint Requests No. 20-23, 25, and 27(b) seek documents concerning particle size, solubility, food effect, and bioavailability of carbamazepine.[1] The obviousness defenses raised by Defendants concern the

[1] Joint Requests No. 52, 53, and 54, which seek documents concerning the marketing and sales of carbamazepine, are discussed in the next section under secondary considerations.

expectation that absorption and bioavailability of a low solubility drug would be affected by the drug's particle size -- namely, that a reduction in particle size would have been expected to increase the rate of drug absorption into the bloodstream. Defendants seek discovery concerning plaintiff's drug carbamazepine (brand name Tegretol®) because it is closely related both structurally and in terms of its low solubility to oxcarbazepine (brand name Trileptal®), the drug at issue in this litigation. Numerous publications, including publications authored by employees of Plaintiffs and their predecessor companies, confirm that carbamazepine, the predecessor drug to oxcarbazepine, is very similar to oxcarbazepine in its physical characteristics and its low solubility. Thus, documents showing, *inter alia*, that Plaintiffs or their predecessor companies were aware of the effect of carbamazepine particle size on solubility, food effect, or bioavailability are relevant both to the validity and the enforceability of the '525 patent, as are documents that show the understanding of those skilled in the art concerning these issues, the different meanings given to "median particle size," and other issues as described below.

Plaintiffs objected to these requests. During the "meet and confers," Plaintiffs stated that they would produce documents which include a comparison of oxcarbazepine to carbamazepine, but that they would not search for documents concerning the effect of particle size on bioavailability, etc., where such documents concern carbamazepine but not oxcarbazepine. Plaintiffs did not argue that such documents are not relevant. Rather, Plaintiffs argued that carbamazepine has been around for four or five decades, so that the documents needing to be searched constitute a "huge universe" of documents, and that such a search would impose an undue burden on them. Plaintiffs now argue that any such documents are not relevant unless they were publicly known, and that Defendants are "equally able as Novartis" to locate any such documents that were publicly known. Novartis is wrong on both points.

(1) A number of carbamazepine documents may be relevant to key issues in this litigation even if they were not "publicly known." Novartis argues that documents concerning carbamazepine that contain information that was not "publicly known" cannot be relevant to the question of validity. Novartis supports this by asserting that Defendants have only argued invalidity based on obviousness, and that information that was not publicly known cannot qualify as prior art. Novartis is mistaken for several reasons.

First, at least some of the Defendants are about to seek to amend their pleadings to add the affirmative defense of "inequitable conduct," based in part on the statement in Novartis's own Swiss patent application -- not translated for the USPTO -- that it was known that an especially small particle size would lead to increased bioavailability. Evidence that Novartis knew that the closely-related drug carbamazepine also had improved bioavailability when its particle size was decreased by micronization would be further evidence that Novartis had information

material to the patentability of the alleged invention in the '525 patent that it did not disclose to the USPTO.

Second, Novartis has itself injected specific issues into the litigation to which documents concerning carbamazepine may well be relevant. In its June 12, 2007, Supplemental Response to Defendants' Joint Interrogatory No. 1, Novartis states that it was "unexpected" that the smaller particle-size oxcarbazepine would avoid the "food effect" and have greater stability against discoloration. Novartis's documents concerning the similar compound carbamazepine may show that these characteristics were not (or should not have been) "unexpected" by Plaintiffs' scientific personnel, and may also reflect that this was the understanding of those of ordinary skill in the art.

Third, Novartis is aware from the joint claim chart submitted to the Court on June 13, 2007, that Defendants maintain that certain of the claims of the '525 patent are indefinite, in particular the claim terms respecting "median particle size." Novartis will no doubt advance a particular definition of this term as the plain meaning as understood by those of ordinary skill in the art. Plaintiffs' documents concerning carbamazepine may well reflect an understanding of median particle size by its own scientists that is contrary to the position taken now by Novartis, and thus would support Defendants' assertion of indefiniteness.

Fourth, Novartis's internal documents concerning carbamazepine may show that if a person of ordinary skill wished to improve the bioavailability of a poorly soluble compound, micronizing the particles was one of "a finite number of identified, predictable solutions." *KSR Int'l Co. v. Teleflex Inc.*, ___ U.S. ___, 127 S.Ct. 1727, 1742 (2007). Because "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp," *id.*, such evidence would support Defendants' position that the '525 patent is invalid due to obviousness.

Fifth, there are certain publicly available Novartis documents concerning carbamazepine that indicate the probable existence of other documents that may be highly supportive of Defendants' position that the effect of particle size on this class of drug was well known. For example, U.S. patent no. 5,122,543 (attached as Exhibit A) was issued in 1992 and was assigned to Plaintiffs' predecessor. This patent notes the rapid absorption of carbamazepine from a syrup in which the carbamazepine particles were less than 10 microns in size, and quotes prior art concerning the "central importance" of particle size in dissolution rate and absorption (i.e., bioavailability). Col. 1, ln. 44-49. In addition, there is no instruction to take the Tegretol with food, from which it appears that there is no significant food effect with such smaller particles. Also, Novartis markets three different Tegretol dosage forms, and it would be expected that Novartis would have comparative studies of dissolution and absorption of its own various forms of carbamazepine.

Such studies may indicate the knowledge of those of ordinary skill in the art, may have been published or presented in one form or another so as to constitute prior art, and may include or refer to materials that would have been material to the patentability of the alleged invention in the '525 patent and so should have been provided to the USPTO.

(2) Novartis is obligated to produce any responsive carbamazepine documents with "publicly known" information, which by its own admission qualify as prior art. Novartis concedes that documents concerning carbamazepine which contain publicly known information do constitute prior art, and thus can be used by Defendants to contest the validity of the '525 patent. But then Novartis asserts that "Defendants are equally able as Novartis in finding it."

This statement is simply wrong. The present litigation does not concern prior art that would only exist in the past ten years or so and thus could perhaps be located in on-line journals and databases. Novartis may be expected to have at least the following types of documents concerning carbamazepine which would qualify as prior art or which would otherwise support Defendants' assertion that the '525 patent is invalid based on obviousness, and which are not equally accessible to Defendants:

(a) Publications by its own scientists, as well as papers, notes of conferences, and other public presentations made by its own personnel concerning the effect of particle size on solubility, bioavailability, or food effect, or the determination of "median particle size";

(b) Similar documents concerning publications or presentations by others on these topics, including publications from European and other sources that are not readily available to Defendants; and

(c) Documents reflecting the expectation of one of ordinary skill in the art with respect to the effect of particle size on solubility, bioavailability, or food effect.

Because Novartis was actively engaged in research and development concerning the poorly soluble compound carbamazepine, it would be expected that Novartis had already gathered publications concerning the particle size and bioavailability of such compounds. Defendants are not "equally able" to assemble such publications after the fact. Nor would such equal ability, if it existed, negate Novartis's obligation to produce such relevant documents in its possession, custody, or control.

(3) The relevance of such documents concerning carbamazepine outweighs any burden on Novartis, which in any case Novartis overstates. From the foregoing it may be seen that a number of Plaintiffs' documents concerning carbamazepine may well be quite relevant to the claims and defenses in

this litigation. Accordingly, Novartis must rely on its argument that a search for such documents would be unduly burdensome. But because such documents as described above would be highly probative with respect to the invalidity of the '525 patent, because Novartis overstates the burden it would incur, and because the rules of discovery and the facts of this case so require, Novartis should be ordered to produce these documents to Defendants.

First, carbamazepine is still produced and marketed by Novartis under the name Tegretol. This drug is still subject to regulation by the FDA and by the regulatory agencies of foreign countries. To comply with FDA requirements, Novartis must keep readily accessible documentation concerning this drug. Accordingly, there must be significant files related to carbamazepine that are maintained in such a way as to facilitate document review. In addition, even the publicly available FDA filings have much information redacted. Such filings, which may include relevant information, would normally be maintained in a way that makes them readily accessible.

Second, Novartis does not have to first review and then produce its documents concerning carbamazepine. Its obligation is only to produce such documents for inspection, at which point Defendants would have the burden of reviewing them.

Third, even if there were a significant burden on Novartis in searching for such documents, it would not be an undue burden in light of the subject matter of this litigation. Novartis has had more than ample time to conduct a search for such documents. Novartis has known for several years that there would be litigation when and if any of its related patent applications was granted in the United States. More particularly, Novartis has been aware since at least February 2004 -- when a European "opposition" proceeding was commenced against the related European patent -- that other parties were basing invalidity arguments on, *inter alia*, studies and information concerning carbamazepine. In addition, Novartis received Defendants' paragraph IV certifications over a year ago, and chose to bring these patent infringement lawsuits more than eight months ago.

Thus, Novartis should not be able to avoid its duty to produce relevant documents in its possession on the basis of "undue burden" when it has had several years' notice that such documents are relevant to the issue of invalidity of its related European patent on fine-particle oxcarbazepine. Nor should Novartis be permitted to avoid a search for documents concerning carbamazepine by pleading "undue expense," when the lack of these relevant Novartis documents may enable it to improperly retain its monopoly on a drug that is earning it $1.5 million each and every day. In short, having chosen to commence these lawsuits in a United States District Court, Novartis must comply with the rule that relevant evidence must be produced. It is simply not the law that a large corporation can commence litigation

and then can avoid searching through its own repository of documents, however large – especially when, as here, the requested documents are relevant and the non-production of these documents may enable Novartis to maintain a multi-million dollar monopoly based on a patent which should not have been granted in the first place.

Plaintiffs' position:

In response to Defendants' joint document request nos. 20-23, 25 and 27(b), Plaintiffs objected to searching for and producing documents that relate solely to the compound carbamazepine, on both relevancy and burdensomeness grounds. The documents that Defendants seek in these requests relate to a compound (carbamazepine) and formulation that is two generations prior to the compound and product covered by the patent-in-suit.

In a nutshell, Defendants present six arguments in support of their position: (1) old, non-public Novartis documents regarding carbamazepine may reveal evidence that "Novartis" committed "inequitable conduct" by withholding information about that compound from the USPTO; (2) old non-public Novartis documents regarding carbamazepine may be relevant to Defendants' assertion that smaller particle sizes of the different compound, oxcarbazepine, were obvious; (3) that old non-public Novartis information may be relevant to Defendants' "indefiniteness" defense; (4) older publicly-available information is more accessible to Novartis than to Defendants; (5) the relevance of the old Novartis carbamazepine documents outweighs any burden on Novartis to produce them; and (6) Novartis "overstates" that burden. Defendants' arguments are unconvincing, are legally irrelevant or are mere exaggeration.

Historical Background

Carbamazepine was first synthesized in the late 1950's. The research and development of a formulation using carbamazepine (in milled form) resulted in a formulation that was approved for marketing in the United States under the trade name Tegretol® in January 1982. Tegretol® is still on the market in the U.S. today.

Oxcarbazepine was first synthesized in 1963, and was found to have fewer side effects than carbamazepine. Scientists at Novartis' predecessor company worked on developing a formulation containing oxcarbazepine (also in milled form), and introduced a product in Europe in the early 1990's under the trade name Trileptal®.

The research that led to the discovery of the effects of using oxcarbazepine of a smaller particle size (milled extra fine) -- and the patent here in suit -- began in the mid-1980's, during the development of a formulation to be introduced in the U.S.

market. Scientists at Novartis' predecessor company discovered that oxcarbazepine of a smaller particle size provides improved bioavailability. In contrast to the prior larger-particle-size oxcarbazepine product sold in Europe, which required administration with food, the smaller-particle-size oxcarbazepine product may be taken with or without food; good bioavailability is achieved in both cases. A formulation using the smaller-sized oxcarbazepine was approved for marketing in the United States in January 2000. The product is sold in the United States under the trade name Trileptal®. It is this product that Defendants are trying to copy by seeking FDA approval for their proposed generic oxcarbazepine products.

Defendants are Not Entitled To Discovery Now On An Unpled Defense ("Inequitable Conduct")

Defendants say that the defense of "inequitable conduct" which "at least some" of them are "about to seek" leave to plead; justifies the huge amount of discovery they seek on the old carbamazepine compound. Defendants are wrong.

First, Defendants' proposed last-minute new defense is not yet even in this case. On that ground alone, the discovery is irrelevant.

Second, what "Novartis" knew as a corporation is irrelevant to the issue of inequitable conduct, which focuses on the acts or omissions of individuals who had a duty of disclosure to the USPTO. *See FMC Corp. v. Manitowoc Co, Inc.*, 835 F.2d 1411, 1415 n.8 (Fed. Cir. 1987). To the extent any individual who had such a duty with respect to the patent-in-suit, had the knowledge alleged by defendants, Novartis believes all relevant non-privileged documents have been produced.

Old Non-Public Novartis Information Is Legally Irrelevant To Obviousness

As much as Defendants try to cook up theories as to why old non-public information may be relevant to obviousness, they continue to ignore the statutory reality that such information does not constitute "prior art" and cannot be relied on to establish obviousness in this case.

Obviousness under 35 U.S.C. § 103 focuses, *inter alia*, on the "prior art" which includes both public and, in certain cases, non-public information. To the extent the old information sought by Defendants was not publicly known, it could only qualify as possible prior art under 35 U.S.C.§ 102 (f) or (g) (derivation and prior secret invention of another). Since that information and the invention of the patent-in-suit were, at the time of such invention, commonly-owned, the information does not constitute "prior art" and therefore cannot be used to establish obviousness of that invention. 35 U.S.C. § 103(c)(1). *KSR Int'l Co. v. Teleflex Inc.*, ___ U.S. ___,

127 S.Ct. 1727, 1742 (2007), is simply inapplicable to the issue of why Section 103(c)(1) makes the information sought legally irrelevant.

Old Non-Public Novartis Information Is Legally Irrelevant to Indefiniteness

The second paragraph of 35 U.S.C. § 112 requires patent claims to be "definite" -- *i.e.*, particularly point out and distinctly claim the subject matter which the inventor regards as his invention. The purpose is to put the public on notice of what the patent covers.

Defendants' defense of indefiniteness is newly-asserted, and Defendants have not provided any explanation of that defense. At a minimum, without knowing the details of the defense, Novartis reasonably cannot be expected to search for documents which may possibly relate to Defendants' unexplained defense.

More fundamentally, however, any "understanding of median particle size by [Novartis's] own scientists" expressed in the old documents sought by Defendants is legally irrelevant. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1585 (Fed. Cir. 1996) (statements by patentee's employees about meaning of claim term are "entitled to no weight in light of the clear contrary meaning shown in the specification").

Defendants' Argument Based On An Unsupported Professed Inability To Search For Publicly-Available Information Is Meritless

The fact that there may be publications among Novartis's old carbamazepine documents sought by Defendants, does not automatically mean that Novartis can easily locate them or that Defendants could not, with the exercise of reasonable diligence, search the public literature for them.

Defendants' professed inability to conduct such a search is pure unsupported exaggeration. First, there are four separate defendants here, with substantial resources, as manifested by the army of lawyers on Defendants' side.

Second, patent infringement defendants and their lawyers routinely scour the public literature in the hope of locating publications that may support their defenses. Defendants are capable of doing so here, notwithstanding their unsupported hyperbole to the contrary.

Third, Defendants' manifest ability to do their own searching should be balanced against the unreasonable burden on Novartis of searching through decades-old files to satisfy Defendants' discovery requests (see below).

The Lack Of Relevance Of The Old Novartis Documents Sought By Defendants Does Not Outweigh Novartis's Huge Burden

The likelihood of finding legally-relevant documents "showing that Plaintiffs or their predecessor companies were aware of the effect of carbamazepine particle size on solubility, food effect or bioavailability" -- which is essentially nil -- is far outweighed by the huge burden of searching through 50 years of research and development records on a compound and product two generations ago. It would take many months and be incredibly expensive to conduct such a search, and the manifest burden of that search would far outweigh the likelihood of finding evidence relevant to this case, even if it were relevant and usable.

Defendants' argument that Novartis has "known for several years" about the likelihood of this litigation and that it should have begun its search then, is meritless. First, foreign opposition proceedings (which occur in foreign patent offices) do not necessarily foreshadow later court litigation in the United States. Second, paragraph IV certifications do not tell the recipient what documents the certifier might possibly later seek in litigation discovery. Novartis justifiably searched for documents after receiving Defendants' document requests. If Defendants' argument was correct, a U.S. patent owner should begin collecting documents for possible U.S. litigation as soon as someone challenges a related patent anywhere in the world. Merely stating that proposition demonstrates its unreasonableness.

Finally, Defendants' tiresome refrain regarding the amount of money Novartis is earning from its sales of Trileptal® is a red herring. Novartis and its predecessor companies invented this drug -- Defendants did not. Moreover, Defendants of course seek FDA approval to sell a generic copy of Trileptal® not purely for societal reasons, but because they want income.

Defendants are not entitled to the archival discovery they seek.

2. Documents Concerning Secondary Considerations.

Defendants' position:

In Joint Requests No. 30-37, Defendants seek documents related to a number of "secondary considerations." In response, Plaintiffs state that they will produce documents concerning only those specific secondary considerations that they maintain support their position of non-obviousness. In the meet and confers, Novartis represented that it would produce documents both supporting and contradicting any secondary considerations on which it might rely to counter Defendants' evidence that the alleged invention of '525 patent was obvious, but argued that it need not produce documents concerning other secondary

considerations. For example, because Plaintiffs have not (yet) stated that they will rely on "commercial success" as a secondary consideration, Plaintiffs' position is that they need not produce any documents concerning or contradicting such commercial success. This is an improper limitation for several reasons. First, the Supreme Court announced in *Graham* that secondary considerations may support both obviousness and non-obviousness. Second, Defendants should be permitted to counterbalance Plaintiffs' secondary considerations as part of the "totality of the evidence" -- this is not a case where there is an "absence" of secondary considerations. Third, even if discovery could be limited to the secondary considerations upon which Plaintiffs choose to rely, fact discovery is still under way and Plaintiffs have specifically stated that they might identify "other secondary considerations as discovery proceeds."

(1) The Supreme Court has ruled that secondary indicia of obviousness should be considered. As a defense to Plaintiffs' allegations of infringement, Defendants have asserted invalidity due to obviousness. Although "secondary considerations" usually arise in the context of indicia of non-obviousness, which may rebut a prima facie case of obviousness, the Supreme Court has ruled that secondary considerations also have relevance as indicia of obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). To the extent that the Federal Circuit may have ignored that ruling over the years, that court has simply been mistaken.

Defendants maintain that the evidence they seek may in fact be indicia of obviousness; as such, they constitute part of the "totality of the evidence"[2] that a court must consider in arriving at its legal conclusion respecting obviousness. At least a few courts have specifically recognized this role for secondary indicia of obviousness. *See Advance Transformer Co. v. Levinson*, 231 U.S.P.Q. 1, 12 (N.D. Ill. 1986) (failed attempts to license constituted a secondary consideration supporting obviousness), *rev'd on other grounds*, 837 F.2d 1081 (Fed. Cir. 1988); *Mattel v. Hyatt*, 206 U.S.P.Q. 499, 522 (C.D. Cal. 1979) (failure to sell or license were "[s]econdary considerations confirm[ing] the obviousness of Hyatt's claimed invention"), *aff'd*, 664 F.2d 757 (9th Cir. 1981). In so doing, these courts followed the teaching set out by the Supreme Court in *Graham*.

(2) This is not a case where there is an "absence" of secondary considerations. Plaintiffs cite several cases for the proposition that the absence of secondary considerations is neutral, and that such absence cannot support a finding that a patent is obvious. Plaintiffs are correct insofar as the cases they cite address the absence of secondary indicia of non-obviousness. But this is not such a case.

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[2] *See, e.g., Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1131 (Fed. Cir. 2000) ("the ultimate determination of whether an invention is obvious is a legal question based on the totality of the evidence").

In their June 12, 2007, Supplemental Responses to Defendants' Joint Interrogatory No. 1, Plaintiffs stated that they will rely on certain secondary considerations. Once these are placed into issue by Plaintiffs, Defendants have the right to counterbalance them. For example, Plaintiffs state that they will rely on "unexpected results," including the avoidance of a "food effect" by the smaller particle-size oxcarbazepine. Defendants seek evidence to counter Plaintiffs' position, which includes evidence of other secondary considerations. For example, documents that establish that there was no "long-felt unmet need" to avoid the food effect, or that establish that any "commercial success" of oxcarbazepine has been independent of its particle size, would undercut Plaintiffs' argument that this particular "unexpected results" was significant enough to outweigh Defendants' evidence showing that the invention was obvious.

(3) In any case, Plaintiffs cannot avoid discovery on other secondary considerations while at the same time reserving their right to add these into the litigation at a later date. In their June 12, 2007, Supplemental Response to Joint Interrogatory No. 1, Plaintiffs objected that this interrogatory was premature because fact discovery was just beginning. Accordingly, in addition to stating that they would rely on the secondary considerations of "unexpected results" and "defendants' copying," Plaintiffs also stated that they "reserve[d] the right to supplement this response with respect to other secondary considerations as discovery proceeds."

Plaintiffs are correct in stating that "fact discovery is just beginning." Thus, even if Plaintiffs were correct that the only relevant secondary considerations were those on which they choose to rely, they cannot forestall discovery of other potentially relevant evidence at this early stage in the proceedings. The question of what evidence will be admissible at trial is an issue for a later day. Furthermore, because Plaintiffs have reserved the right to add other secondary considerations later, based on discovery, Defendants must not be precluded from obtaining evidence now which they might need to contest any such later assertions by Plaintiffs.

Thus, in keeping with the pronouncement in *Graham* that inquiries into secondary considerations may be relevant "[a]s indicia of obviousness or nonobviousness" (*id.* at 18), Novartis should produce documents concerning all of the secondary considerations included in the Joint Requests. For the same reasons, Plaintiffs should produce documents responsive to Joint Requests No. 49-51 and 57-59 (concerning worldwide sales, advertisements, projections, and industry data relating to oxcarbazepine and other drugs "labeled for use in the treatment of seizures, bipolar disorder and/or epilepsy"), and Joint Requests No. 52, 53, 54, and 56 (which concern similar requests directed to the marketing and sales of carbamazepine).

Plaintiffs' position:

As it previously advised Defendants, Novartis will not rely on the secondary consideration of commercial success to support the non-obviousness of its claimed invention. Thus, no documents related to this issue could possibly be relevant.

The *Graham* case outlined the basic factual inquiries that must be determined in order to assess obviousness under 35 U.S.C. § 103: determine the scope and content of the prior art, ascertain the differences between the prior art and the claims at issue, and resolve the level of skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). Secondary considerations "might be" utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. *Id.* Secondary considerations (or objective evidence) "may often establish that an invention appearing to have been obvious in light of the prior art was not." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983).

Later decisions of the Federal Circuit clarify that the *lack* of secondary considerations, such as evidence of "a lack of commercial success" or "no long-felt unmet need", does not support a finding of obviousness. *See, e.g., Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870, 878 (Fed. Cir. 1993) ("[objective indicia of non-obviousness] if present, would weigh in favor of non-obviousness, although the lack of such evidence does not weigh in favor of obviousness"). Defendants' reliance on *Graham* therefore is misplaced.

The absence of any secondary considerations would not support an obviousness finding, as Defendants contend – at best, it is considered a "neutral factor", and thus irrelevant. *Medtronic, Inc. v. Intermedics*, 799 F.2d 734, 739 n.13 (Fed. Cir. 1986) (the absence of objective evidence of long felt need and commercial success is a neutral factor); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1478 (Fed. Cir. 1998); *Custom Accessories, Inc. v. Jeffrey-Allen Ind., Inc.*, 807 F.2d 955, 960 (Fed. Cir. 1986) ("absence of objective evidence does not preclude a holding of non-obviousness because such evidence is not a requirement for patentability").

This makes sense. The presence of real-world objective secondary considerations tends to prove that what is asserted to have been obvious, in fact was not. But the absence of such facts does not prove obviousness; logically, the absence of such positive factors merely means there is no objective evidence supporting a conclusion of non-obviousness.

Defendants cannot derail binding precedent from the Federal Circuit, a Court tasked with handling all patent appeals, by relying on stale statements from two inapposite decisions. First, by calling the Federal Circuit "simply . . . mistaken",

Defendants improperly dismiss its teachings. Defendants' authority, which no other court has ever cited for these propositions in the more than two decades since they were decided, cannot support the erroneous proposition that secondary considerations can be used to support obviousness -- a position contradicted by the caselaw cited by Plaintiffs. *See, e.g., Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870, 878 (Fed. Cir. 1993). It is Defendants that are simply mistaken.

Advance Transformer Co. v. Levinson, 231 U.S.P.Q. (BNA) 1 (N.D. Ill. 1986), *vacated in relevant part,* 837 F.2d 1081 (Fed. Cir. 1988), is inapposite. The Federal Circuit vacated the entire district court determination that the patent was invalid, thereby vacating the very proposition upon which Defendants now rely. 837 F.2d at 1084.[3]

Defendants citation to *Mattel v. Hyatt*, 206 U.S.P.Q. 499, 522 (C.D. Cal. 1979), *aff'd,* 664 F.2d 757 (9th Cir. 1981), is equally misplaced, because the court there did not use evidence of lack of secondary considerations to *create* a prima facie case of obviousness, as Defendants are trying to do here. Moreover, the Ninth Circuit recited the *Graham* test used by the district court for finding the patent obvious -- a discussion notably devoid of the secondary consideration factors. 664 F.2d at 760 n.2.

The secondary considerations of non-obviousness on which Plaintiffs have chosen not to rely are therefore not relevant to this litigation. Defendants are not entitled to this discovery.

3. Plaintiffs' Response Concerning the "Detailed Statements" Submitted to Them by Third Parties.

Defendants' position:

Defendants' Joint Request No. 72 requests the production of "[a]ll documents and things concerning any generic oxcarbazepine product or ANDA for any oxcarbazepine product, including, but not limited to any Notice of Certification pursuant to 21 C.F.R. § 314.95 or related statute received by or on behalf of any plaintiff regarding any oxcarbazepine product or Trileptal®" This is directed to the statutory requirement that an ANDA applicant that files a paragraph IV certification must provide to the patent-owner a "detailed statement of the factual and legal basis of the opinion . . . that the patent is invalid or will not be infringed."

Plaintiffs first argued that any such detailed statement provided by an ANDA-filer which is not a party to these lawsuits is not relevant. Plaintiffs have now offered

[3] Because the Federal Circuit held that the patent was not infringed, it was not necessary for the Court to assess the ruling on the patent's invalidity and therefore vacated the determination on this point. Id.

to provide "a list of prior art found in the detailed statements of third parties," and assert that any other information in these detailed statements is not relevant. However, in addition to the mere citations to prior art, the detailed statements of third parties are relevant to the claims and defenses in these lawsuits for other reasons as well:

(1) The detailed statements may provide scientific interpretations by the third parties of the prior art which they reference;

(2) The detailed statements may also contain legal arguments based on this prior art, which may be reinforced by the particular scientific understanding expressed by that third party;

(3) The detailed statements may further contain one or more legal bases "that the patent is invalid" which are not related in any way to obviousness or the prior art cited in the statement;

(4) The existence of a number of detailed statements, and the strength of their factual and legal bases for asserting that the '525 patent is invalid, is evidence that the Court should consider when deciding Plaintiffs' as well as Defendants' claims that these lawsuits should be declared "exceptional cases"; and

(5) The reasons presented by third parties for non-infringement of their oxcarbazepine tablets may also be relevant to the issue of non-infringement in these lawsuits.

Accordingly, the contents of all the detailed statements provided by third parties to Novartis are relevant to the claims and defenses in these actions, and Novartis has provided no reason why they should not be produced. If there is a concern about the confidentiality of such detailed statements provided by third parties, any such concern may be addressed by designating these as "Highly Confidential -- Outside Counsel Only Information" pursuant to the Discovery Confidentiality Order.

Plaintiffs' position:

Defendants are not entitled to know the identities of third parties who may have submitted paragraph IV certifications in connection with the Trileptal® product. Generic companies seeking approval to market a generic version of an approved prescription drug must notify the New Drug Application holder and owner of any listed patent if they intend to seek approval prior to the expiration of the listed patent. 21 U.S.C. § 505(j)(2)(B) and 21 C.F.R. § 314.95. These certifications include statements regarding their proposed product as well as reasons why they believe the patent is not valid or not infringed by their product. Paragraph IV filers

share this information for the sole purpose of complying with these statutes and regulations. To the extent the paragraph IV certifications have been designated by the paragraph IV filers as "Confidential," this information cannot be shared with others, including the Defendants, without the consent of the third parties. As Defendants can appreciate, the information contained in a paragraph IV certification may contain details about the components of the proposed generic product, as well as the process of manufacturing that product. The Defendants would not want their information shared with others, much less with competing generic companies. In fact, Defendants Breckenridge, Taro and Teva each marked their paragraph IV certifications to Novartis as "Confidential".

Plaintiffs offer provides Defendants with the information they are entitled to while preserving the confidentiality of any third parties.

B. Plaintiffs' issue with regard to Production of Samples of Defendants' ANDA Products:

Plaintiffs' position:

Almost one month ago, Plaintiffs served their Second Set of Requests for the Production of Documents and Things ("Second Requests") which seek production of samples of Defendants' ANDA product, including their tablets, active ingredient, and documents or things related to the manufacture of these tablets and the active ingredient. Defendants Breckenridge, Teva and Roxane have refused to provide samples.

Defendants both refuse to concede infringement and to provide the requested samples. Plaintiffs require these samples so that particle size testing can be performed on them to carry Plaintiffs' burden of proving infringement. Defendants cannot have it both ways -- they should not be allowed to continue to assert non-infringement and at the same time refuse production of the samples Plaintiffs need to prove infringement. Therefore, Defendants should be ordered to produce the samples called for in Plaintiffs' Second Requests, or to withdraw their non-infringement defense.

Defendants' position that they will "shortly" respond is unavailing. To the extent they continue their refusals, the Court should order production of the samples and other discovery.

Defendants' position:

Plaintiffs misstate the response to their request for samples. Defendants have not refused to provide samples while also refusing to concede infringement.

Plaintiffs did not serve their request for samples until June 14 (which at that point was just prior to the time for submitting discovery disputes to the Court). A response is due on July 16. Just as Novartis has informed Defendants of its difficulty in scheduling timely depositions because of Swiss work and vacation schedules, certain defendants have yet to obtain a response from their clients. Defendants all expect to provide responses shortly to Plaintiffs' request.

C. Plaintiffs' issues regarding Defendants' Objections to Plaintiffs' Contention Interrogatories as "premature"

Plaintiffs' position:

On January 12, 2007, Plaintiffs served their First Set of Interrogatories seeking Defendants' contentions regarding the basic issues in the case: validity, enforceability and infringement of the '525 patent. Defendants' objections, that such interrogatories are premature, are improper. Defendants were obligated months ago to provide a Notice Letter which set forth the basis of their opinions on these issues. Plaintiffs are entitled to Defendants' present contentions on these issues.

Plaintiffs should not be required to wait until the end of fact discovery or expert discovery to know the detailed reasons for Defendants' assertions that the '525 patent is invalid, not enforceable, or not infringed. *See, e.g., Braun Med. Inc. v. Abbott Labs.*, 155 F.R.D. 525, 527 (E.D. Pa. 1994) (compelling defendant, prior to end of discovery, to answer contention interrogatories thereby disclosing the prior art which supported its obviousness claim because the "prior art interrogatories will serve to clarify the issues and narrow the scope of the dispute"); *AstraZeneca AB v. Mutual Pharm. Co.*, 278 F. Supp. 2d 491, 507 (2003) (merely listing references in a contention interrogatory without providing detailed bases did not put Plaintiffs on notice and give Plaintiffs an opportunity to take discovery). Such issues go to the core of this litigation, and Defendants' responses are insufficient in this respect. For example:

(1) Roxane's General Objection 5 states that "Roxane objects to each interrogatory as premature to the extent that it seeks information in advance of the time periods provided in the PRETRIAL SCHEDULING ORDER. . . including but not limited to the last day parties may supplement contention interrogatories (October 2, 2007). . . ." Roxane's General Objection cannot allow it to avoid providing answers which the Court has ordered. More specifically, Interrogatory Nos. 2 and 3 to Roxane seek Defendant's detailed analysis of the invalidity of the '525 patent based upon 35 U.S.C. §§ 1, et seq. and 35 U.S.C. § 103, respectively. Roxane claims that its answer, which is nothing more than a list of prior art, is sufficient. However, this position is directly contrary to *AstraZeneca AB v. Mutual Pharm. Co.*, 278 F. Supp. 2d 491, and

Roxane should now supplement its answers to this and other Interrogatories so that the parties can narrow the issues between them.

(2) Interrogatory Nos. 2 and 3 to Breckenridge seek Defendant's detailed analysis of the invalidity of the '525 patent based upon 35 U.S.C. § 102 and 35 U.S.C. § 103. Breckenridge only refers Plaintiffs to its Paragraph IV Notice Letter, served in May 2006 and, like Roxane, provides a legally insufficient list of prior art without any detailed assertions of the relevance of these publications. *See AstraZeneca AB v. Mutual Pharm. Co.*, 278 F. Supp. 2d 491. It is nonsensical to believe that, more than one year later, more than halfway through fact discovery and with the aide of Plaintiffs' document production, Breckenridge's present positions on invalidity are unchanged from its May 2006 Notice Letter.

(3) In Interrogatory No. 1, Plaintiff seeks Taro's contentions regarding infringement. Taro's objection that a response is "premature in that the plaintiffs have not set forth there [sic] interpretation of the meaning of the terms set forth in the claims. . ." is now unfounded, as the parties have submitted their Joint Claim Chart. Taro's failure to supplement this response continues to go unexplained. Taro now contends that its advice of counsel defense is relevant to its Response to Interrogatory No. 1, but yet Taro has failed to provide any reason why it has delayed in supplementing its Response with this information. Additionally, Interrogatory Nos. 2 and 3 seek Taro's detailed bases for its belief that the patent is invalid for failure to satisfy 35 U.S.C. §§ 1, et seq. and 35 U.S.C. § 103. Taro's duplication of its May 2006 Notice Letter in those responses without further narrowing or clarifying the issues of alleged invalidity is, as with Breckenridge, insufficient. More than one year later, more than halfway through fact discovery and with the aide of Plaintiffs' production, Taro must have clarified its position on the critical invalidity issues in this case, and Plaintiffs are entitled to that information.

(4) Teva's Response to Interrogatory Nos. 1-4 state that Plaintiffs' Interrogatories regarding infringement, invalidity and unenforceability are "premature" because "[r]esponses to contention interrogatories are appropriate only after discovery has been substantially completed". Teva states that its "investigation continues." Plaintiffs recognize that Teva may supplement its answers as its investigation continues, but such continued analysis does not prevent Teva from disclosing the results of its investigation to date. Interrogatory Nos. 2 and 3 relate to Teva's contentions that the '525 patent is invalid pursuant to 35 U.S.C. §§ 101, et seq. and 35 U.S.C. § 103. As with the other Defendants, it is difficult to believe that, more than one year later, more than halfway through fact discovery and with the aide of Plaintiffs' production, Teva's

present positions on invalidity are unchanged from and best explained by its May 2006 Notice Letter.

The Court's Scheduling Order required that discovery begin in January 2007 and interrogatories be served and responded to shortly thereafter. The scheduling order contemplates that "[c]ontention interrogatories shall be supplemented no later than October 2, 2007" (Scheduling Order at I.3.B, emphasis added), which means that substantive responses must be exchanged prior to that time. A clear statement of Defendants' contentions on these core issues now can only help to clarify and narrow the issues. There is good reason for Defendants to provide substantive responses to interrogatories now.

Defendants' position:

First, Defendants note that Plaintiffs, in their June 12, 2007, Supplemental Response to Defendants' First Joint Set of Interrogatories, continue to object to Interrogatory No. 1 and 2 as premature (while providing some information in response to No. 1). Defendants and Plaintiffs are both under an obligation to supplement their responses to the extent necessary, and to do so by October 2, 2007.

Second, Plaintiffs mischaracterize Defendants' responses to Plaintiffs' contention interrogatories. Defendants did not merely object to all of Plaintiffs' contention interrogatories as premature and provide no response, as Plaintiffs seem to suggest. Defendants provided substantive responses to many of Plaintiffs' contention interrogatories. For example:

1. Roxane Responses to Plaintiffs' Interrogatories Nos. 2 and 3 provided all prior art of which Roxane was aware that related to the invalidity of the '525 patent under 35 U.S.C. §§ 101 and 103. Roxane Response to Plaintiffs' Interrogatory No. 4 provided that Roxane was not aware of any other bases as to the noninfringement, invalidity or unenforceability of the '525 patent other than a possible claim of unenforceability which it was actively pursuing. As Roxane indicated in its response, if and when additional bases were developed, the interrogatories would be updated to reflect Roxane's then contentions.

2. Breckenridge's Responses to Plaintiffs' Interrogatories Nos. 2 and 3 similarly provided a list of all prior art of which Breckenridge was aware that related to the invalidity of the '525 patent under 35 U.S.C. §§ 102 and 103. Breckenridge will shortly inform Novartis in detail of its contentions concerning inequitable conduct, and will supplement its response to the interrogatories as required.

3. Taro's Responses to Plaintiffs' Interrogatories Nos. 2 and 3 provided a detailed analysis of all prior art of which Taro was aware that related to the invalidity of the '525 patent under 35 U.S.C. §§ 1 *et seq.* and 35 U.S.C. § 103. Taro's Response to Plaintiffs' Interrogatory No. 5 provided Taro's basis for asserting that this case be declared exceptional. As to Taro's response to Interrogatory No. 1, as Taro advised Novartis on July 6, 2007, Taro will be supplemented in part its prior response when it produces its advice of counsel opinion which it has agreed to do.

4. Teva's Responses to Plaintiffs' Interrogatories Nos. 1-4 provided that the bases for Teva's contentions regarding non-infringement and invalidity were set forth in its Detailed Statement which had previously been provided to Novartis. Teva's response to Plaintiffs' Interrogatory No. 5 provided Teva's basis for asserting that this action is an exceptional case. As indicated in its responses, Teva's investigation is still continuing and Teva will supplement its interrogatory answers as appropriate.

Moreover, Defendants previously provided Plaintiffs with a substantial amount of information that is responsive to their interrogatories through Defendants' Detailed Statements of the factual and legal bases of their Paragraph IV certifications. Additionally, fact discovery is still on-going and expert discovery has not yet begun. Accordingly, Defendants are continuing to develop their positions in the litigation. The Court, in its PRETRIAL SCHEDULING ORDER, set October 2, 2007 as the deadline for supplementing contention interrogatories. Defendants will abide by this deadline and will continue to supplement their responses if and when they become aware of additional information that is responsive to Plaintiffs' interrogatory requests, subject to the provision in Fed. R. Civ. P. 26(e)(2) that a party need not formally supplement its responses unless "the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing."

D. Defendants' issues regarding Plaintiffs' Objections to Defendants' Interrogatories as "irrelevant"

Defendants' Position:

On April 9, 2007, Defendants served on Plaintiffs their First Joint Set of Interrogatories Nos. 1-6. Interrogatory No. 3 requested the identification of any and all factors and things Plaintiffs considered in deciding to initiate the lawsuit including but not limited to opinions of counsel, prosecution documents for the '525 patent and related U.S. and foreign applications, detailed statements and the identification of people most knowledgeable about these considerations. In their response, Plaintiffs objected to Interrogatory No. 3 on privilege and relevance grounds. Plaintiffs' claim that the information sought is protected by attorney-client privilege lacks merit as to the identity of the factors considered by Plaintiffs, and with

respect to Defendants' request that Plaintiffs identify the people most knowledgeable about these considerations. The information requested in Interrogatory No. 3 is also highly relevant because it directly relates to Defendants' claim that this case is exceptional pursuant to 35 U.S.C. § 285. As such, Plaintiffs' objections are improper.

Interrogatory No. 2 of Defendants' First Joint Set of Interrogatories requested that Plaintiffs identify worldwide sales for each and every oxcarbazepine product sold by Plaintiffs. Plaintiffs objected to this interrogatory on relevance grounds. According to Plaintiffs' theory, their decision not to rely on the commercial success of the Trileptal® oxcarbazepine product as an objective secondary consideration of non-obviousness automatically disposes of the issue of commercial success in the current litigation and therefore any discovery request related to sales of the Trileptal® oxcarbazepine product is irrelevant. For the same reasons discussed above in section A.2, Plaintiffs are mistaken, and should be required to provide the information requested.

Plaintiffs' position:

With regard to Interrogatory No. 3, Novartis offered to withdraw the relevancy objection (but maintain its privilege objection) and identify the things Novartis considered in deciding to initiate these lawsuits provided that Defendants would agree not to assert that the answer constitutes a waiver of any attorney-client privilege or work product. Defendants stated that they would not agree to allow Novartis to rely on advice of counsel or include substantive advice of counsel in the interrogatory response without providing that advice of counsel and all associated documents. Novartis repeated that the response to the interrogatory would not be used by Novartis to rely on advice of counsel or to "include substantive advice of counsel" (since Novartis had already taken the position not to rely on advice of counsel). Novartis maintains that their offer was reasonable, and will answer, if Defendants provide their non-waiver agreement.

Novartis has already provided Defendants with a list of individuals involved with the decision to file the instant lawsuits. In addition to being provided with a list of names, Defendants also had an opportunity to ask Novartis's Rule 30(b)(6) designee about these individuals and the meetings that were held to discuss the decision to file the instant lawsuits.

With regard to Interrogatory No. 2, Novartis maintains that Defendants are not entitled to the identity of worldwide sales for each and every oxcarbazepine product sold by Novartis since Novartis will not rely on commercial success as a secondary consideration of non-obviousness in this case. For the reasons stated by